K113164

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

MAR 1 1 2013

A. General Information

1. Submitter's Name.:	OTTO BOCK Health Care, LP
2. Address:	Two Carlson Parkway North, Suite 100
	Minneapolis, Minnesota USA 55447-4467
3. Telephone:	763-253-5614
4. Contact Person:	Angie Zhang, Regulatory Affairs Specialist
5. Date Prepared:	November 13, 2012
6. Registration Number:	2182293

B. Device

1. Name:	Discovery Tmax Manual Wheelchair
2. Trade Name:	Discovery Tmax Manual Wheelchair
3 .Common Name:	Manual Wheelchair
4. Classification Name:	Wheelchair, Manual
5. Product Code:	IOR
6. Class:	I
7. Regulation Number:	890.3850

C. Identification of Legally Marketed Predicate Device

1. Name:	FUZE MECHANICAL WHEELCHAIR, MODEL T50
2. Manufacture:	PDG PRODUCT DESIGN GROUP, INC.
3. K Number:	K063736
4. Date Cleared:	01/17/2007

D. Description of the Device

The Discovery Tmax is a manually operated, self/attendant propelled, mechanical wheelchair. It is intended exclusively for the adaptation of orthopedic seating systems (e.g. seating shells) for people who are unable to walk or have walking impediments. The Discovery Tmax can be used indoors and outdoors. In order to provide an optimized, individual fitting, the product is adjustable and/or adaptable.

The Discovery Tmax consists of a non-folding frame of aluminum, large wheels with hand rims, and small front pivoting casters. The width, depth, and height of seat are adjustable in 1 inch increments. The armrest is made of Polyurethane soft integral foam and is adjustable. It also has an adjustable backrest and removable footrest.

The Discovery Tmax includes a "Tilt in space" feature which allows the seat to be tilted. The seat angle can be adjusted from -5° to +50° in increments of 2.5°. The desired seat angle is achieved by moving the push handles/ push bar. The angle can be read from the angle indicator on the hole channel.

Features

- Available in a version for children and in three adult sizes
- Suitable for use indoors and outdoors
- Pneumatic or flat-free front and rear wheels available
- Width, depth and height of seat adjustable in 1 inch increments
- Cable-free, maintenance-friendly seat angle release with foot pedal and release lock
- Smooth seat angle adjustment without pneumatic spring thanks to adjustable centre of gravity
- Can be combined with various seating units:
  -OBSS® custom contoured cushions
  -NUTEC custom seating systems
  -Standard wheelchair back systems
  -Standard wheelchair cushions
- 50° Tilt in Space
- Aluminum Frame
- Transit Tie Down
- Seat Pan
- Armrest
- Armpad
- Anti-tipper
- Wheel lock
- Push handles
- Front Rigging
- Footrests
- Calf Strap
- Heel Strap
- casters
- Rear Wheels

E. Intended Use Statement

The wheelchair is intended exclusively for the adaptation of seating shells and other orthopaedic seating systems for people who are unable to walk or have walking impediments. It can be operated either by the user or by an attendant.

F. Indications

The Tmax wheelchair are suitable for patients with walking impediments/inability due to, but not limited to:

- Palsies/Paralyses
- Loss of limbs
- Defective and/or deformed limbs
- Joint contractures
- Joint defects
- Other diseases

G. Substantial Equivalence

The Discovery Tmax Wheelchair is substantially equivalent to PDG's FUZE Mechanical Wheelchair, Model T50 (K063736)

H. Performance Data

The Discovery Tmax manual wheelchair was tested by TUV SUD, Institute for Testing and Certification of Medical Devices to the following standards:

- DIN EN 12182:1999 – Technical aids for disabled persons
- DIN EN 12183:1999 – manually propelled wheelchairs – requirements & test methods
- ISO 7176-1:1999 – Wheelchairs – Part 3: Determination of static stability
- ISO 7176-3:2003 – Wheelchairs – Part 3: Determination of efficiency of brake
- ISO 7176-5: 2008-Wheelchairs – Part 5: Determination of overall dimensions, mass and maneuvering space
- ISO 7176-7:1998 – Wheelchairs – part 7: Measurement of seating & wheel dimensions
- ISO 7176-8:1998 – Wheelchairs – Part 8: Requirements, static impact/fatigue strengths
- ISO 7176-11: 1992- Wheelchairs – Part 11: Test dummies
- ISO 7176-13: 1989 Wheelchair – Part 13: Determination of coefficient of friction of test surfaces
- ISO 7176-15:1996 – Wheelchairs – Part 15: Requirement for labeling
- ISO 7176-16: 1997 Wheelchairs – Part 16: Resistance to ignition of upholstered parts-Requirements and test methods
- ISO 7176-19:2008 – Wheelchairs – Part 19: Wheeled mobility devices for use in motor vehicles

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 11, 2013

Otto Bock Healthcare
% Mr. William Kabitz
2 Carlson Parkway N., Suite 100
Minneapolis, Minnesota 55447

Re: K113164
Trade/Device Name: Discovery Tmax Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: February 21, 2013
Received: March 5, 2013

Dear Mr. Kabitz

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Otto Bock®
QUALITY FOR LIFE

APPENDIX F

Indications For Use Form

510(k) Number (if known): To be determined

Device Name: Discovery Tmax Manual Wheelchair

Indications for Use:

The Tmax wheelchair are suitable for patients with walking impediments/inability due to, but not limited to:

- Palsies/Paralyses
- Loss of limbs
- Defective and/or deformed limbs
- Joint contractures
- Joint defects
- Other diseases

Prescription Use ____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Brian D. Pullin -S

Division of Neurological and
Physical Medicine Devices
510(k) Number: K113164